Testimony of James Scanlon
Acting Deputy Assistant Secretary for Science and Data Policy
Department of Health and Human Services
before the
U.S. House of Representatives Government Reform Committee,
Subcommittee on Regulatory Affairs

July 20, 2005

Good morning, Madame Chairman and Members of the Subcommittee. I am James Scanlon, Acting Deputy Assistant Secretary for Planning and Evaluation and Director of the Office of Science and Data Policy within the Office of the Secretary at the Department of Health and Human Services. Thank you for the opportunity to testify about the implementation of the Information Quality Act (IQA) in the Department of Health and Human Services (HHS).

HHS administers more than 300 programs. Comprised of ten large and diverse Operating Divisions, including the NIH, CDC, FDA, and the federal Medicare and Medicaid agency, HHS is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially to those who are least able to help themselves. In the course of carrying out their program missions, HHS agencies disseminate a wide variety of information to the public, ranging from research and statistical reports to expert and authoritative health and medical information. Many of these dissemination products rank among the most highly regarded and highest quality scientific, research and statistical information within the federal government, and in many instances they set the national and international standards for quality.

Consequently, HHS is committed to supporting, developing and disseminating information consistent with the objectives of the Information Quality Act. It has long been an HHS goal to ensure that the best available scientific and technical information is used to support regulatory and programmatic decision making.

Requirements of the Information Quality Act

In 2001, Congress enacted the Information Quality Act (IQA), which directed the White House Office of Management and Budget to issue government wide guidelines that provide policy and procedural guidance for ensuring and maximizing the quality, objectivity, utility and integrity of information, including statistical information, that the agency disseminates to the public. OMB issued its Guidelines in February 2002.

The OMB Guidelines in turn directed federal agencies to do three things:

1. Issue their own agency information quality guidelines by October 1, 2002;
2. Establish administrative mechanisms allowing affected persons to seek and obtain correction of information disseminated by the agency that they believe does not comply with the Guidelines; and
3. Report to the Director of OMB annually regarding the number and nature of correction requests that the agency receives and how such requests were resolved.

HHS Implementation of the Information Quality Act

Within HHS, we developed and issued our *HHS Guidelines for Ensuring the Quality, Objectivity, Utility and Integration of Information Disseminated to the Public* in October 2002, and created an extensive HHS information quality website to support implementation. All of the information I will be discussing this morning is available on the HHS information quality website: http://www.aspe.hhs.gov/infoquality. In implementing the IQA within HHS, we took several approaches that may differ from other agencies. First, we implemented the IQA through the science policy and data policy channels within HHS. Second, it became obvious early on that a "one size fits all" approach would not work within HHS, and we developed HHS wide umbrella Guidelines accompanied by agency-specific Guidelines within the HHS framework. However, our Guidelines incorporate standard HHS wide standards and procedures whenever possible, including the administrative request for correction mechanism.

Third, we created a department-wide HHS Information Quality Working Group to ensure a coordinated and integrated approach across HHS, assure implementation in a manner appropriate to agency statutes and missions, and build upon existing agency administrative procedures and data and scientific quality review mechanisms.

Fourth, within HHS, we implemented the Information Quality Act by working closely with OMB and our stakeholders in the health and human services communities, including a notice and public comment process on draft Guidelines .

The *HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public* were developed within the framework of the OMB Guidelines. The purposes of the HHS Guidelines are to provide policy and procedural guidance to agency staff, and to inform the public about agency policies and procedures. Part I of the HHS Guidelines describes department-wide umbrella policies, guidelines and operating procedures. Part II of the HHS Guidelines describes component agency-specific guidelines in order to address specific program statutes and missions for operating divisions such as the Centers for Medicare & Medicaid Services, the Food and Drug Administration and the National Institutes of Health. Responsibility for implementing the Guidelines within HHS Operating Divisions rests with the head of the agency or program unit disseminating the information.

Overall departmental level responsibility for oversight and coordination of the implementation of the Guidelines within HHS rests with the Office of the Assistant Secretary for Planning and Evaluation. In addition, oversight and coordination across HHS is supported by our department-wide work group, led by the Office of Secretary and composed of senior representatives from all HHS Operating Divisions.

The HHS Information Quality Work Group was created to assure maximum sensitivity and understanding of the underlying science and data issues that might be raised within a very large federal science and public health agency with complex and diverse programs. It also was created as a mechanism to achieve an integrated departmental implementation of the Information

Quality Act by developing a uniform HHS set of principles and Guidelines format, a forum for addressing common issues and approaches, and a means to provide on-going monitoring of implementation problems and issues. HHS views the Guidelines as an evolving document and information quality as an evolving process.

As I indicated, our Guidelines contain an administrative complaint mechanism that allows affected persons to seek and obtain correction of information that they believe does not comply with the Guidelines. We established a common format for submitting information quality requests for corrections and requests for reconsideration (i.e., appeals) to HHS agencies.

Generally, the HHS approach calls for requesters to submit requests for correction that contain:

- a detailed description of the specific material that needs to be corrected;
- the specific reasons for believing the information is in error and supporting documentation, if any;
- the specific recommendations for correcting the information; and
- a description of how the person submitting the request is affected by the information error.

The HHS website contains instructions about how to submit a request for correction and identifies the official to whom requests are to be submitted. Although our goal is to respond to all requests for correction within 60 calendar days of receipt, our experience is that actual

response times generally are considerably longer because of the extensive expert staff time involved and the wide array of agency scientific and legal reviews are involved in developing a response. In cases where the request requires more than 60 calendar days to resolve, HHS informs the requestor that more time is required and indicates the reason why and an estimated decision date.

HHS Operating Divisions assign requests for corrections to individuals who have a high level of expertise in the subject area of the information dissemination that is being challenged. Both Information Quality Work Group and operating division staff closely monitor the development of responses to requests and reconsiderations in order to encourage expeditious treatment. The requestor may appeal (i.e., request a reconsideration) within 30 days of receipt of the HHS decision.

Our position on appeals is very liberal; we consider any request for reconsideration that is submitted. The HHS Guidelines require that the agency official who handles the original request "will not have responsibility for resolving the appeal." Generally, the appeal is handled at least one level above the originating office. In most cases, very senior level agency officials have responded to appeals, including the Commissioner of the Food and Drug Administration, the Deputy Director of the National Institute of Environmental Health Sciences, NIH, the Director of the National Heart, Lung and Blood Institute, NIH and the Associate Director for Science in the Centers for Disease Control and Prevention.

Experience with the Correction Process

Since the October 2002 effective implementation date of the HHS Guidelines, HHS has received 22 information quality requests for correction and 13 requests for reconsideration. Requests have been submitted by a variety of interested parties including trade associations, industry, advocacy groups, and private citizens. A number of organizations have submitted multiple requests to HHS as well as to other federal agencies. All the requests and HHS responses are posted at http://aspe.hhs.gov/infoquality The requests concern a wide range of HHS information. They include challenges to the following:

< CDC information on water fluoridation;

< NIH information on the health effects of smokeless tobacco;

< A number of National Toxicology Program background documents, including naphthalene, vinyl chloride, nickel and others;

< The HHS scientific evaluation of medical marijuana;

< Information on the U.S. Dietary Guidelines; and

< FDA information on the use of fluoroquinolones (i.e., antibiotics) in poultry feed.

All requests for correction and for reconsideration are taken very seriously by the agency. Here are three examples of requests that resulted in some corrective action:

< A request to CDC from a private citizen resulted in the redirection of a link on the CDC website to general information (rather than to only technical information) on gonorrhea.

< A request to the National Institute of Aging, NIH from the National Legal and Policy Center concerning the risk of using smokeless tobacco as compared to smoking cigarettes resulted in revised language that described the risk associated with using smokeless tobacco products without making an affirmative comparison of those risks to the risks associated with smoking cigarettes.

< A request to the National Toxicology Program from the Styrene Information and Research Center concerning information on the styrene manufacturing process in a fact sheet and press release resulted in a revised statement about the uses of Styrene-7,8-oxide.

HHS Information Quality Website

To ensure transparency and ease of use, HHS has created a department-wide data quality website at http://www.aspe.hhs.gov/infoquality. The website includes: 1) the HHS and agency specific Guidelines, 2) a short, user-friendly summary of HHS information quality requests for corrections and reconsiderations, 3) the data quality correction requests submitted to HHS along with the agency responses, 4) the HHS Annual Information Quality Reports to OMB, and 5) links to all agency Guidelines and agency Information Quality contacts.

Thank you for the opportunity to testify. I would be happy to answer any questions you may have.